Guidelines for Data Collection & Data Entry

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Outline and references

▷ Steps to data collection and entry:

1. Create your data dictionary.
   - **BEFORE** any data is collected.
2. Create your data file(s).

▷ References:

- *Designing Clinical Research* (3rd edition) by Hulley, et al.
- "The Little Handbook of Statistical Practices" – Gerard Dallal.
  - http://www.tufts.edu/~gdallal/LHDP.HTM
- "10 Data Entry Commandments" and "Spreadsheets from Heaven/Hell" from Daniel W Byrne, MS.

Step 1:

Create your data dictionary

Introduction

▷ **Before** *any data is collected*, write a detailed list of the information to be collected and the concepts to be measured in the study.

- Directly relates to the specific aim(s) of the study.
- Make sure the list includes all the information needed to
  1. describe the *sample* of "subjects" you will study
  2. perform the planned statistical analysis.[1]
- If using a questionnaire, make sure all the necessary information is collected in the questionnaire.

▷ The collected data items will be stored as *variables*.

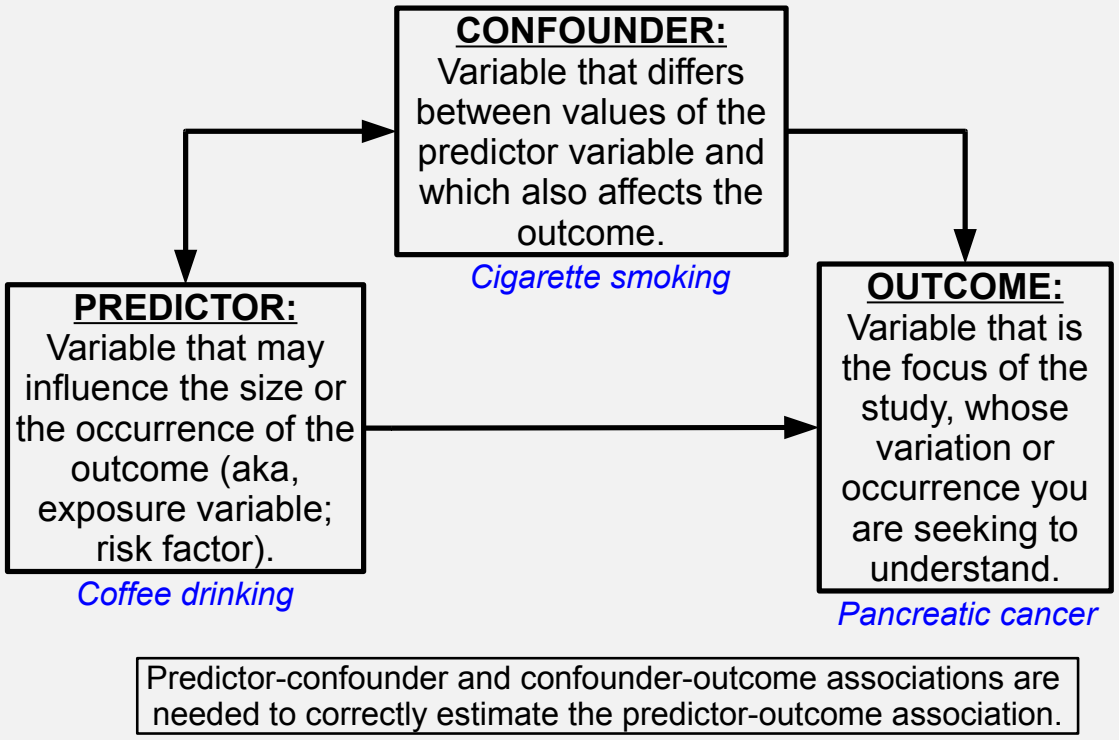
▷ Helpful to define the role of each variable:

- Outcome, predictor, confounder, or additional descriptor[2].

[1] Meet with your statistician.

[2] Used to describe your sample of "subjects."

Role of collected variables



Predictor-confounder and confounder-outcome associations are needed to correctly estimate the predictor-outcome association.

Convert the detailed list to a *data dictionary*

▷ A document that includes a description of the study variables and data management procedures.

▷ For each variable, it includes the

- variable name,
- role of the variable (in the statistical analysis),
- variable label,
- unit of measurement (if applicable),
- type of variable,
- permissible values or range of values
- definitions of redefined and derived variables
- additional edits to be performed (eg, logic/consistency checks).

▷ Should be created *before* any data are collected.

- Expect revisions and review with your statistician.

The data dictionary in more detail

- **Variable name:** used to identify the variable in the *data file(s)*.
  - Should be short but understandable/self-explanatory.
- **Variable label:** "Pretty" label to fully describe the variable.
  - Example: "Age at baseline".
- **Type of variable:**
  - **Continuous:** has any number of possible values (eg, weight).
    - **Discrete numeric** – set of possible values is a finite (ordered) sequence of numbers (eg, pain scale of 1, 2, . . . , 10).
  - **Categorical:** has only certain possible values (eg, race).
    - **Binary** (**dichotomous**) – a categorical variable with only two possible values (eg, gender).
    - **Ordinal** – a categorical variable for which there is a definite ordering of the categories (eg, severity of lower back pain as none, mild, moderate, and severe).

The data dictionary in more detail, *cont'd*

- **Permissible values:** (for categorical variables)
  - Can be coded as numeric or text values.
  - Example: For gender (a binary variable)
    - Numeric coding: 0 (Female) and 1 (Males).
    - Text coding: "F" (Female) and "M" (Male).
  - Which to use depends on the target statistical program.
- **Permissible range of values:** (for continuous or discrete numeric variables)
  - Purpose: to guide data editing – values outside the defined range must be checked for accuracy.
- **Redefined/derived variables:** should be (re-)calculated by your statistician (eg, BMI).

Additional considerations

- ▷ Continuous variables: Keep continuous, don't categorize.
  - If collected categorized, original continuous values can't be recovered and can't recode with new categories.
- ▷ Be consistent with
  - Text coding of categorical variables – many statistical programs are case-sensitive (eg, "M" $\neq$ "m").
  - Date formats (eg, mm/dd/yyyy).
  - Representation of missing values (eg, blank or NA).
- ▷ Break up *non-mutually exclusive* values.
  - Example: Maternal complications of bleeding, high blood pressure, and fever can occur in any combination.
    - Code as three separate Yes/No columns of bleeding, high blood pressure, and fever (instead of a single text field).

Example data dictionary

Name	Role	Label	Units	Type	Values
GROUP	Predictor	Treatment		Binary	1 = Placebo; 2 = Treatment
AGE	Predictor	Age	Years	Continuous	18 - 75
SEX	Predictor	Gender		Binary	1 = Female; 2 = Male
HT	Predictor	Height	in.	Continuous	48 - 96
WT	Predictor	Weight	lbs.	Continuous	75 - 350
HCT	Predictor	Heart rate	beats/min.	Continuous	30 - 50
BPSYS	Predictor	Systolic BP	mmHg	Continuous	100 - 160
BPDIAS	Predictor	Diastolic BP	mmHg	Continuous	80 - 150
STAGE	Predictor	Stage of cancer		Discrete numeric	1 - 4
RACE	Predictor	Race		Categorical	1 = White; 2 = Black; 3 = Other
DATE1	Additional	Date of surgery			mm/dd/yyyy
COMPLIC	Outcome	Complications?		Binary	0 = No; 1 = Yes

Step 2:

Create your data file(s)

Introduction

▷ Most common and easily accessible approach to creating your data file(s) is to use a *spreadsheet* program, like Microsoft Excel.

- Easy to enter the data values directly into the appropriate cells (rows and columns) using a keyboard.

▷ Other possible data entry programs: STATA, SPSS, Microsoft Access, EpiInfo, and REDCap (more in a bit).

▷ *CAUTION!* Not good enough that data is merely entered into a spreadsheet.

- Data often are entered without an eye toward statistical analysis.
- Many spreadsheets require considerable cleaning before they are suitable for analysis.
- There are ways to enter data so that they are nearly unusable – the Spreadsheet from Hell.

Spreadsheet from Hell

Comparison of Drug A and Drug B								
Drug A	Age of Patient	Patient Gender	Height (inches)	Weight (pound)	blood pressure	tumor stage	Race	Date enrolled
1	25	Male	61"	>350	120/80	2-3	Hipanic	1/15/99
2	65+	female	5'8"	161	140/90	II	White	2/05/1999
3	?	Male	120cm		>160/110	IV	Black	Jan 98
4	31	m	5'6"	obse	140 sys 105 dias	?	Afr-Amer	?
5	42	f	>6 ft	normal	missing	=>2	W	Feb 99
6	45	f	5.7	160	80/120	NA	B	last fall
7	unknown	?	6	145	normal	1	W	2/30/99
8	55	m	72	161.45	120/95	4	Afr-Amer	6-15-00
9	6 months	f	66	174	160/110	3	Asian	14/12/00
10	21	f	5'					
Drug B								
1	55	m	61	145	120/80 120/90	IV	Nat Amer	6/20/
2	45	f	4"11	166	135/95	2b	none	7/14/99
3	32	male	5'13"	171	140/80	not staged	NA	8/30/99
4	44	na	65	?	120/80	2	?	09/01/00
5	66	fem	71	0	140/90	4	w	Sep 14th
6	71	unknown	172	199	>160/110	3	b	unknown
7	45	m	?	204	140 sys 105 dias	1	b	12/25/00
8	34	m	NA	145	130	3	w	July 97
9	13	m	66	161	166/115	2a	w	06/06/99
10	66	m	68	176	1120/80	3	w	01/21/58
Average	45		65	155				

Data entry guidelines

▷ *Goal:* Create your data file(s) to achieve

1. a smooth transfer between a spreadsheet and a statistical program package
2. optimal statistical analysis.

▷ *Standard data structure:* A table of numbers and text in which each row corresponds to an individual subject (or unit of analysis) and each column corresponds to a different variable or measurement.

- One record (row) per subject.
- Example: For a study that recorded the identification number, age, sex, height, and weight of 10 subjects, the resulting data file would be composed of 10 rows and 5 columns.

Data entry guidelines, *cont'd*

▷ Data structure for *repeated measurements* on the same subject (or unit of analysis).

- Example: A study where 5 weekly blood pressure readings are made on each of 20 subjects.
- Two options: a "wide" data file or a "long" data file.
  - "Wide": 20 rows and 6 columns (5 blood pressures and an ID).
    - Still have one record (row) per subject.
  - "Long": 100 rows of 3 columns (ID, week number (1-5), and blood pressure).
    - Have 5 records (rows) per subject.
  - Which option to use will depend on the target statistical program.

Data entry guidelines, *cont'd*

▷ *First row* of the spreadsheet should contain only (legal) *variable names*.

- Definition of "legal" will vary with the target statistical program.
- All programs will accept variable names that are no more than 8 characters long, are composed *ONLY* of letters, numbers, and underscores, and begin with a letter.
- Good idea to name all variables using lower case, which is easier to type and eliminates mistakes that can occur if software programs are case sensitive (e.g., "Age" vs "age").
- Each variable name should be unique.

▷ Actual data values begin on the *second row*.

Data entry guidelines, *cont'd*

▷ Assign each subject (or unit of analysis) a *unique identifier* (ID; eg, 1, 2, 3, etc).

- Because of HIPAA, the statistician is not allowed to receive data files containing any identifiers.
  - Includes patient name (first, last, or initials), social security number, medical record (MR) number, street address, and telephone numbers.
  - IDs should not contain any of this information.
- Create a separate file that matches the identifying information for each subject (unit of analysis) with their unique ID.
  - Place the assigned unique IDs in the *first column* of your data file(s) to distinguish the subjects on each row.
  - OK to have identifying info in your data files(s) for yourself during data entry; just need to remove it before you send it to your statistician.

Data entry guidelines, *cont'd*

▷ No text should be entered in a column intended for numbers – ie, *don't mix text and numbers in the same column*.

- This includes notations such as "<20", "20+" and "20%".
- If text strings are present, the statistical package may consider all of the data to be text strings rather than numbers.
- In addition, numerical data may be mistakenly identified as text strings when one or more spaces are typed into an otherwise empty cell.
- Exception to this rule: entering text values that distinguish missing data (eg, NA).

Data entry guidelines, *cont'd*

▷ There should be *no embedded formulas*.

- The statistical programs may not be able to handle them.
- Also, the calculated value of a formula is replaced with a blank cell when the spreadsheet is exported as a delimited text file.
- There are two ways to deal with formulas:
  1. Rewrite the formulas in the target package so the statistics package can (re-)generate the values.
  2. Use Microsoft Excel's "Paste Special" capabilities to store the derived values as actual data values in the spreadsheet.
     - Still a good idea to double-check the calculated values in the target statistical package.

Data entry guidelines, *cont'd*

▷ When a study will generate *multiple data files*:

- Every record in every data file must contain a subject (or unit of analysis) identifier that is consistent across all files.
- Data files that are likely to be merged should not use the same variable names (other than the common ID variable).

▷ For studies that generate repeated measurements on the same subject (or unit of analysis), multiple data files often make data entry and management easier.

- One data file contains the information that is not repeatedly collected (eg, demographics such as age, race, and gender; 1 record per), the other data file(s) contain(s) the information that is repeatedly collected (eg, blood pressure collected every week for 5 weeks; "long" format of $\geq$1 record per).

Data entry guidelines, *cont'd*

- How *missing data* is recorded must be carefully considered.
  - Can use a single value to record missing data across all rows and columns.
    - Example: "NA", ".", or a blank cell.
    - Possible problems with specific choice of value:
      - Example: If missing data are coded as "99" and the statistician is not aware of this, a subject who has a missing value for age may be analyzed as if their age is 99 years.
  - Can use several values depending on nature of the data or desire during the analysis.
    - Example: Use ".a" for missing, ".b" for don't know, and ".c" for values that are not applicable.
      - In the analysis, all these values are treated as missing, but the reason the data are missing is retained.

Spreadsheet from Heaven

CASE	GROUP	AGE	SEX	HT	WT	BPSYS	BPDIAS	STAGE	RACE	DATE1
1	1	25	1	61	350	120	80	3	3	1/15/1999
2	1	65	2	68	161	140	90	2	1	2/5/1999
3	1	25	1	47	150	160	110	4	2	1/15/1998
4	1	31	1	66	161	140	105	2	2	4/1/1999
5	1	42	2	72	177	130	70	2	1	2/15/1999
6	1	45	2	67	160	120	80	1	2	3/6/1999
7	1	44	1	72	145	120	80	1	1	2/28/1999
8	1	55	1	72	161	120	95	4	2	6/15/2000
9	1	0.5	2	66	174	160	110	3	4	12/14/2000
10	1	21	2	60	155	190	120	2	2	11/14/2000
11	2	55	1	61	145	120	80	4	5	6/20/1999
12	2	45	2	59	166	135	95	2	1	7/14/1999
13	2	32	1	73	171	140	80	1	1	8/30/1999
14	2	44	2	65	155	120	80	2	2	9/1/2000
15	2	66	2	71	145	140	90	4	1	9/14/1999
16	2	71	1	68	199	160	110	3	2	1/14/1999
17	2	45	1	69	204	140	105	1	2	12/25/2000
18	2	34	1	66	145	130	75	3	1	7/15/1997
19	2	13	1	66	161	166	115	2	1	6/6/1999
20	2	66	1	68	176	120	80	3	1	1/21/1998

Invaluable resource: REDCap

▷ REDCap = *R*esearch *E*lectronic *D*ata *Cap*ture.
▷ Free, secure, web-based application designed exclusively to build online surveys and databases & to support their subsequent data capture and management.
▷ Advantages include

- Easy to use.
- Fast and flexible setup.
- Structured data entry & validation (including automatic type & range checking, calculated fields, & embedded branching logic).
- Multi-site access.
- Ability to export data to common analysis packages (SAS, Stata, R, and SPSS).
- Mid-study modifications possible.
- Ability to import data from external sources.

REDCap, *cont'd*

▷ Wesbite: `https://redcap.vanderbilt.edu`

- Login with your VUNetID and password.

▷ If havent done so already, first check out the

- (1) "Training Resources" tab (series of videos that teach you the basics)
- (2) "Help & FAQ" tab
- Both also available via links within each database

▷ *REDCap (201) Clinic* in MCN D-2221

- 1st & 3rd Thursday of every month from 10:30 AM – 12:00 PM
- 2nd & 4th Tuesday of every month from 2:00 – 3:30 PM
- Co-ran with Janey Wang (member of the REDCap Team)